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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/601,490	09/21/2000	Desire Jose Collen	702-001463	5827
7590	11/03/2003		EXAMINER RAMIREZ, DELIA M	
Barbara E Johnson 700 Koppers Building 436 Seventh Avenue Pittsburgh, PA 15219-1818			ART UNIT	PAPER NUMBER
			1652	21

DATE MAILED: 11/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/601,490

Applicant(s)

COLLEN, DESIRE JOSE

Examiner

Delia M. Ramirez

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 31-67 is/are pending in the application.
- 4a) Of the above claim(s) 31-38,42,44,48-50 and 52-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 39-41,43,45 and 61-67 is/are rejected.
- 7) ☒ Claim(s) 46-47,51 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 November 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 19.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Status of the Application***

Claims 31-67 are pending.

Applicant's amendment of claims 39-41, 43, 45-47, 61-62 and addition of claims 63-67 in Paper No. 20, filed on 8/13/2003 is acknowledged.

As indicated in previous Office Action Paper No. 17, mailed on 2/11/2003, claims 31-38, 42, 44, 48-50 and 52-60 were withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to an invention non-elected without traverse in Paper No. 9, filed 6/21/01. A complete reply to the final rejection must include cancellation of non-elected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

### ***Information Disclosure Statement***

1. The information disclosure statement (IDS) submitted on 8/13/2003 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### ***Claim Objections***

2. Claims 46 and 67 are objected to because of the recitation of "selected amino acids in the NH<sub>2</sub>-terminal region of 10 amino acids ( SEQ ID NO: 1 positions 1-10)". For clarity, it is suggested that the term be replaced with "selected amino acids within positions 1-10 of SEQ ID NO: 1". Appropriate correction is required.

***Claim Rejections - 35 USC § 112, Second Paragraph***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 43 and 63-67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is necessitated by Applicant's amendment.

5. Claim 43 is indefinite in the recitation of "the staphylokinase derivative as claimed...having a reduced absorption of ..antibodies from plasma.., without reducing the specific activity" as it is unclear and confusing. As written, the term "without reducing the specific activity" is unclear since one cannot determine what is being limited by this term. If the term refers to the specific activity of the staphylokinase derivative claimed, the term is also indefinite since it is a relative term for which no basis for comparison has been recited. It is suggested that if the term refers to the staphylokinase derivative claim and the reduction in activity is in relation to that of the wild-type staphylokinase, the claim be amended to recite "the staphylokinase derivative of claim 39 wherein said staphylokinase derivative has a reduced....antibodies from plasma .....and wherein said staphylokinase derivative has the same specific activity as that of the staphylokinase of SEQ ID NO: 1" or similar. For examination purposes, the suggested language will be used. Correction is required.

6. Claim 63 (claims 64-67 dependent thereon) is indefinite in the recitation of "monoclonal antibodies having specific reactivity with staphylokinase" as it is unclear which antibodies are being recited. As written, one cannot determine the specificity of the antibodies since the term "having specific reactivity with staphylokinase" does not provide any clue as to which is the staphylokinase with which these antibodies will react. For examination purposes, it will be assumed that the term's intended meaning is "monoclonal antibodies having specific reactivity with the staphylokinase of SEQ ID NO: 1". Correction is required.

***Claim Rejections - 35 USC § 112, First Paragraph***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 61 remains rejected and newly added claims 63-67 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection and it is necessitated by Applicant's amendment.

9. This rejection has been discussed at length in Paper No. 17 and is now applied to newly added claims 63-67 for the reasons of record and for the reasons set forth below. It is noted that while claim 61 was inadvertently omitted from the listing of rejected claims in Paper No. 17, page 6, paragraph 14, first line, it was clearly rejected as containing new matter as indicated in Paper No. 17, page 6, paragraph 15.

10. Applicant argues that claim 39 has been amended such that no new matter has been introduced.

11. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the rejection in regard to claim 61 or avoid the rejection on newly added claims 63-67. Claim 61 was rejected as containing new matter in view of the recitation of "surface-exposed residue". While Applicant acknowledges that the Examiner indicated that this limitation was not supported in the specification (Applicant's response page 15, last three lines), no amendment to claim 61 was made to overcome the rejection and Applicant has provided no indication as to where can one find support for the term in the specification. As such, the rejection is maintained for the reasons of record. In regard to newly added claims 63-67, these claims are directed to staphylokinase derivatives comprising an amino acid sequence which differs from that of SEQ ID NO: 1 in that at least one amino acid has been substituted with another

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amino acid and wherein polyethylene glycol has been coupled to an amino acid residue at a position outside both the binding epitope and the activation epitope. While the specification indicates that preferred embodiments of the staphylokinase derivatives are those where Cys is chemically modified with polyethylene glycol (page 5, line 28- page 6, line 3), no support could be located for polyethylene glycol coupled to an amino acid residue at a position outside both the binding epitope and the activation epitope nor there is any teaching in the specification as to where these epitopes are in the polypeptide of SEQ ID NO: 1. There is no mention in the specification of the genus of staphylokinase derivatives in the amended claims as preferred embodiments of the instant invention. Applicant is required to cancel the new matter in the reply to this Office Action.

12. Claims 39-41, 43, 45, 61-62 remain rejected and newly added claims 63-66 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is necessitated by Applicant's amendment.

13. This rejection has been discussed at length in Paper No. 17 and is now applied to newly added claims 63-66 for the reasons of record and for the reasons set forth below.

14. Applicant argues that the arguments presented by the Examiner in regard to this rejection are now moot in view of amendment of claim 39. Applicant also asserts that dependent claims are now amended such that they recite which amino acids of SEQ ID NO: 1 must be substituted to obtain 50% specific activity of wild-type staphylokinase and that newly added claim 63 requires both amino acid substitution and pegylation.

15. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the rejection of claims 39-41, 43, 45, 61-62 or to avoid the rejection of newly added claims 63-65. Claims

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39-41, 43, 45 and 62 are directed to a genus of staphylokinase derivatives wherein any number of amino acids in the staphylokinase of SEQ ID NO: 1 can be substituted with a cysteine residue such that a homodimer of the staphylokinase derivative can be made. Claims 40 and 43 add the limitation that the staphylokinase derivatives would have reduced absorption of SakSTAR specific antibodies. Claim 41 adds the limitation that the staphylokinase derivatives have at least 50% the specific activity of the corresponding wild-type staphylokinase. Claim 61 is directed to a genus of staphylokinase derivatives wherein any surface exposed residue can be substituted with Cys. Claim 63 is directed to a genus of staphylokinase derivatives comprising an amino acid sequence which differs from that of SEQ ID NO: 1 in that any number of amino acids can be substituted, wherein said staphylokinase derivatives have reduced reactivity towards antibodies against the staphylokinase of SEQ ID NO: 1 (see above for claim interpretation) and wherein said derivatives are coupled with polyethylene glycol at a position outside both the binding epitope and the activation epitope. Claims 64-65 are directed to the genus of staphylokinase derivatives of claim 63 with the added limitation that the amino acids are substituted with Cys. Claim 66 is directed to the genus of staphylokinase derivatives of claim 63 with the added limitation that the amino acids substituted are surface exposed residues.

While the specification discloses staphylokinases which are derivatives of the staphylokinase of SEQ ID NO: 1 wherein some amino acid residues have been replaced with Cys and wherein polyethylene glycol has been linked to some residues of such derivatives, the specification fails to disclose (1) other amino acids which can be used to substitute any amino acid in the polypeptide of SEQ ID NO: 1 such that they have reduced reactivity against the antibodies recited in the claims and have similar staphylokinase specific activity to that of the corresponding wild-type staphylokinase, (2) which amino acids in the staphylokinase of SEQ ID NO: 1 can be replaced with Cys such that homodimers can be made, (3) which amino acids in the staphylokinase of SEQ ID NO: 1 can be replaced with Cys such that at least 50% of the specific activity of the corresponding wild-type staphylokinase is maintained, (4)

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which are the binding and activation epitopes in the staphylokinase of SEQ ID NO: 1, (5) which are the surface exposed residues in the polypeptide of SEQ ID NO: 1 and which of these residues can be substituted without losing activity. As indicated in previous Office Action Paper No. 17, the state of the art teaches that small structural changes can result in major functional changes. See the teachings of Broun et al., Van de Loo et al. and Seffernick et al. already discussed. The specification only discloses a few species of the genera of staphylokinase derivatives claimed which is insufficient to put one of ordinary skill in the art in possession of all attributes and features of all species within the genera. Thus, one skilled in the art cannot reasonably conclude that Applicant had possession of the claimed invention at the time the instant application was filed.

16. Claims 39-41, 43, 45, 61-62 remain rejected and newly added claims 63-66 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for staphylokinase derivatives of the staphylokinase of SEQ ID NO: 1 wherein selected amino acids within positions 1-10 of SEQ ID NO: 1, charged residues, threonine residues or serine residues within SEQ ID NO: 1 have been substituted with cysteine, does not reasonably provide enablement for staphylokinase derivatives of the staphylokinase of SEQ ID NO: 1 wherein any amino acid has been substituted with any residue, any amino acid has been substituted with cysteine, or any surface exposed residue has been substituted with cysteine. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. This rejection is necessitated by Applicant's amendment.

17. This rejection has been discussed at length in Paper No. 17 and is now applied to newly added claims 63-66 for the reasons of record and the reasons set forth below.



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18. Applicant argues that the claims as amended clearly define the scope of the claimed staphylokinase derivatives. As such, the claims contain limitations that provide sufficient guidance that precludes undue experimentation for the preferred embodiments of the invention.

19. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the rejection of claims 39-41, 43, 45, 61-62 or avoid the rejection of newly added claims 63-66. The scope of the claims as amended and newly added claims, as described above, is not commensurate with the enablement provided in view of lack of information as to (1) other amino acids which can be used to substitute any amino acid in the polypeptide of SEQ ID NO: 1 such that they have reduced reactivity against the antibodies recited in the claims and have similar staphylokinase specific activity to that of the corresponding wild-type staphylokinase, (2) which amino acids in the staphylokinase of SEQ ID NO: 1 can be replaced with Cys such that homodimers can be made, (3) which amino acids in the staphylokinase of SEQ ID NO: 1 can be replaced with Cys such that at least 50% of the specific activity of the corresponding wild-type staphylokinase is maintained, (4) which are the binding and activation epitopes in the staphylokinase of SEQ ID NO: 1, (5) which are the surface exposed residues in the polypeptide of SEQ ID NO: 1 and which of these residues can be substituted without losing activity. As indicated in previous Office Action Paper No. 17, the state of the art teaches that small structural changes can result in major functional changes. See the teachings of Broun et al., Van de Loo et al. and Seffernick et al. already discussed. Since the structure of a protein determines its functional characteristics, one would require some knowledge or guidance as to how the structural elements of the polypeptide of SEQ ID NO: 1 are related to the functional characteristics recited in the claims, i.e. reduced reactivity towards the recited antibodies, at least 50% of the specific activity of the corresponding wild-type staphylokinase. Therefore, one of skill in the art would have to go through the burden of undue experimentation in order to determine which of the large number of staphylokinase derivatives of the staphylokinase of SEQ ID NO: 1 encompassed by the claims have the additional characteristics recited in the claims. For the

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reasons set forth above and those previously indicated, one cannot reasonably conclude that the specification provides sufficient information to enable one of skill in the art to make and/or use the invention in a manner reasonably correlated with the scope of the claims.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

20. Claims 39-41 and 43 rejected under 35 U.S.C. 102(e) as being anticipated by Behnke et al. (US Patent No. 5,801,037, filed on June 30, 1994, published on September 1, 1998). This rejection is necessitated by Applicant's amendment of claims 39-41 and 43.

21. This rejection was previously applied to claims 39-41 in Office Action Paper No. 13, mailed on 5/7/2002. In view of Applicant's amendment submitted in Paper No. 15, filed on 11/12/2002, this rejection was withdrawn. As clearly indicated in Paper No. 17, it was assumed from Applicant's response that Applicant asserted that position 26 is within the "binding epitope" and in view of the fact that the claims were further limited in regard to the location of the amino acid substitution with Cys, the teachings of Behnke et al. were no longer considered applicable prior art. In view of Applicant's

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amendment submitted in Paper No. 20, filed on 8/13/2003, this rejection is now reintroduced since amended claims 39-41 and 43 are now directed to any staphylokinase derivative of a staphylokinase comprising the amino acid sequence of SEQ ID NO: 1 wherein any amino acid is substituted with a cysteine residue. There are no limitations in regard to which amino acids can be substituted with Cys in the amended claims. Behnke et al. teaches a staphylokinase variant of SEQ ID NO: 1 wherein a methionine residue at position 26 has been substituted with a cysteine residue (column 8, lines 60-61), therefore the staphylokinase of Behnke et al. anticipates the claims as written.

### *Double Patenting*

22. Claims 39-41, 43, 45, 61-62 remain rejected and newly added claims 63-66 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3-5 of U.S. Patent No. 6383483. This rejection has been discussed at length in Paper No. 17, mailed on 2/11/2003 and is applied to newly added claims 63-66 for the reasons of record.

23. Claims 39-41, 43, 45, 61-66 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-17 of copending Application No. 09/728670. It is noted that this rejection was previously made in Paper No. 17 over claims 7-8 of copending Application No. 09/728670. Claims 7-8 of copending Application No. 09/728670 have been cancelled and claims 13-17 have been added for examination in such application.

24. Claims 39-41, 43, 45 and 62 of the instant application are directed to any staphylokinase derivative wherein any number of amino acids in the staphylokinase of SEQ ID NO: 1 can be substituted with a cysteine residue such that a homodimer of the staphylokinase derivative can be made. Claims 40 and 43 of the instant application add the limitation that the staphylokinase derivatives would have reduced absorption of SakSTAR specific antibodies. Claim 41 of the instant application adds the limitation that the staphylokinase derivatives have at least 50% the specific activity of the corresponding wild-type

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staphylokinase. Claim 45 adds the limitation that the polyethylene glycol is up to 20 KDa in molecular weight. Claim 61 of the instant application is directed to any staphylokinase derivative wherein any surface exposed residue, charged residue, threonine residue or serine residue can be substituted with Cys. Claim 63 of the instant application is directed to any staphylokinase derivative comprising an amino acid sequence which differs from that of SEQ ID NO: 1 in that any number of amino acids can be substituted, wherein said staphylokinase derivatives have reduced reactivity towards antibodies against the staphylokinase of SEQ ID NO: 1 (see above for claim interpretation) and wherein said derivatives are coupled with polyethylelene glycol at a position outside both the binding epitope and the activation epitope. Claims 64-65 of the instant application are directed to the staphylokinase derivatives of claim 63 with the added limitation that the amino acids are substituted with Cys. Claim 66 of the instant application is directed to the staphylokinase derivatives of claim 63 with the added limitation that the amino acid substituted are surface exposed residues, charged residues, threonine residues or serine residues.

Claim 13 of copending Application No. 09/728670 is directed to any staphylokinase derivative of the staphylokinase of SEQ ID NO: 10 (same as SEQ ID NO: 1 in the instant application) having the coding regions of sakOC or sak42D (only 4 nucleotides differences among the polynucleotides encoding SEQ ID NO: 10, sakOC and sak42D according to the specification, page 1, lines 20-32), further having one or more amino acids substituted with cysteine residues and further having polyethylene glycol groups coupled to them. Claim 14 of copending Application No. 09/728670 is directed to the staphylokinase derivative of claim 13 wherein the amino acid substituted is that at position 102 of SEQ ID NO: 10 and wherein it has polyethylene glycol coupled to it. Claim 15 of copending Application No. 09/728670 is directed to the same staphylokinase derivatives of claim 13 with the added limitation that the staphylokinase derivatives have at least 50% the specific activity of the corresponding wild-type staphylokinase. Claim 16 of copending Application No. 09/728670 is directed to staphylokinase

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derivatives of the staphylokinase of SEQ ID NO: 10 (same as SEQ ID NO: 1 in the instant application) with specific amino acids being substituted. Claim 17 of copending Application No. 09/728670 is directed to staphylokinase derivatives of the polypeptide of SEQ ID NO: 10 as indicated in Figure 3 further comprising polyethylene glycol groups coupled to them and having less absorption of SakSTAR specific antibodies. Figure 3 is the same in both the instant application and that of copending Application No. 09/728670.

The specification of copending Application No. 09/728670 discloses SakSTAR derivatives K109C and K102C as embodiments which provide support for claim 13-17 and it also discloses the pegylation of K102C as an embodiment which provides support for claim 14. Furthermore, the specification of copending Application No. 09/728670 also discloses that derivatives K109C, K102C, and K102-PEG (derivative K102C pegylated with a 5 KDa polyethylene glycol) have specific activities which are comparable to that of the corresponding wild-type staphylokinase (SakSTAR; SEQ ID NO: 10) and also teaches that these derivatives have reduced absorption of SakSTAR specific antibodies. Also, the amino acid at position 109 is a Lys residue (prior to substitution with Cys), which is a charged residue. Furthermore, according to the teachings of Jespers et al. (Thromb. Haemost. 81:479-485, April 1999; cited in the IDS), positions 102 or 109 of SakSTAR are not part of the binding or activation epitopes of SakSTAR. Therefore, one of skill in the art would conclude that the invention of claims 39-41, 43, 45, 61-66 of the instant application is anticipated by and/or an obvious variation of the invention in claims 13-17 of copending Application No. 09/728670 since the embodiments disclosed and/or the claims of copending Application No. 09/728670 are the subject matter being claimed in the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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25. Applicant has indicated that assignments will be recorded in due course and a proper terminal disclaimer in compliance with 37 CFR 1.321(c) will be filed in due course. In view of Applicant's response and for the reasons set forth above, these rejections are maintained for the reasons of record.

*Allowable Subject Matter*

26. Claims 46-47 and 51 are allowable over the prior art of record but they are objected to since they depend upon rejected claim 45.

*Conclusion*

27. No claim is in condition for allowance.

28. Applicant's amendment of claims 39-41, 43, 45-47, 61-62 and addition of claims 63-67 necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

29. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 308-4556. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (703) 306-0288. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (703) 308-3804. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Delia M. Ramirez, Ph.D.  
Patent Examiner  
Art Unit 1652

DR  
October 21, 2003

  
REBECCA E. PROUTY  
PRIMARY EXAMINER  
~~21504-1503~~  
1600